Commentary: an imperfect compromise

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Boter and colleagues have proposed a compromise to obtaining fully informed consent before enrolment for randomised trials that have primary outcomes based on a subjective measure, which makes blinding impossible and bias likely. This compromise aims to involve the patient and show them as much respect as possible. As with all compromises it is imperfect. From the trialists' point of view it still has several drawbacks compared with obtaining consent only for follow up.

Telling patients that there is a secret additional research question is likely to reduce the proportion of patients who agree to participate and thus the generalisability of the trial's results. The number of patients who refused to participate in the study, and their characteristics compared with participants, would indicate the size of this problem.

The wording of the patient information is bound to raise curiosity about the nature of the additional questions. Some participants may make the link between the intervention they receive and the questions asked at follow up. This would introduce an unknown amount of bias, although it is likely to be small.

The reassurance given to patients that the "additional question entails no risk" is potentially misleading. Firstly, if the intervention improves outcome then those in the control group will have a risk of a worse outcome. This statement could therefore be used only when the patient would have access to the intervention only within the trial and where the control arm would receive normal care. Also, in our trial, those allocated a stroke family care worker judged themselves more helpless than controls at follow up. We have subsequently shown that helplessness in these stroke patients was associated with poorer long term survival, even after we adjusted for important prognostic factors.[1] No treatment should be assumed to be free of adverse effects. Perhaps the reassurance should read that there are no likely adverse effects.

No doubt the ethicists, who focus mainly on the rights of the individual, will see this compromise as unacceptable. They do not have to struggle with the everyday double standards applied to consent procedures in research compared with those in routine care and audit. We have no universally accepted solution to the clinical trialists' dilemma that to provide treatments of proved benefit to many future patients (and to avoid putting them at risk) we may sometimes have to compromise the rights of current patients to be fully informed in advance about treatment options and research methods.

Of course, we shouldn't have to rely on what the ethicists or the trialists think. Surely, we should involve potential participants in the design of the consent procedure. We should ask the patients who were enrolled in this study for their views. Did they feel, once they had been informed, that they had been treated with respect? Was the approach taken in this case acceptable to them?

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1 Lewis SC, Dennis MS, O'Rourke SJ, Sharpe M. Negative attitudes among short-term stroke survivors predict worse long-term survival. *Stroke* 2001;32:1640-5.

A memorable patient

Compartment syndrome

The 6 year old boy arrived in the night with a painful and swollen elbow after a fall. His supracondylar fracture was manipulated, the subsequent x ray films looked excellent, and he was discharged. He returned two days later with severe pain and a blistered, swollen forearm. The diagnosis of compartment syndrome crossed my mind, but my registrar soon ruled it out. He said, "Swelling is quite common in this fracture. The child's pulses are palpable, and sensations are fine. Send him home." Being a beginner, I did not have enough clinical knowledge and experience to challenge the decision. Who would challenge his senior, anyway? Hence the child was discharged the second time with a follow up appointment in the clinic after two days.

This patient's subsequent visit was the most devastating experience of my professional life. He was reviewed in the clinic by my professor (who eventually turned out to be the architect of my future orthopaedic career). As luck would have it, the senior registrar was on annual leave that day—good for him, bad for me. The puffy forearm had all the signs of a well established compartment syndrome (and a "neglected" one), with no movement, pulses, or sensations. My professor was furious. His words burnt my ears like molten lead. I stood before him like a culprit in a witness box with my hands tied behind my back. There were no pauses and no opportunities for explanations. In those few minutes of constant fire, I saw my clinical career collapsing like a house made of playing cards. I was almost in tears, and I felt guilty, worthless, and incompetent.

The subsequent decompression was obviously unsuccessful, and the child developed Volkmann's ischaemic contracture.

I knew this stigma would remain with me forever. And so it did. The story was told over and over again to each new group of undergraduate and postgraduate students. It was referred to as "Dr Anwar's case." My boss always emphasised the importance of early identification of this condition. Interestingly, my registrar would always nod his head in agreement like a true disciple without sensing the red hot rage in my chest.

Ten years later, when I visited my professor in India, I tried to clear my name by explaining things to him again. He replied: "My boy, what happens when you see a child with a supracondylar fracture of the humerus now? You remember me, you remember that child, and you remember compartment syndrome. That is what it was all about." I will never forget those golden words that were so true and meaningful.

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